SUMMARY OF SAFETY AND EFFECTIVENESS

ALARIS Medical Systems, Inc. K022209

SUBMITTER INFORMATION

Company: ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, CA 92121

Contact Person: Renée L. Fluet
Principal Regulatory Affairs Specialist
Phone: (858) 458-7563
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Date Summary Prepared: July 3, 2002

DEVICE CLASSIFICATION

This Special 510(k) premarket submission will not require a change to current device classification. This submission only affects the Administration Set portion of ALARIS Medical Infusion Systems. The Administration Sets remain in the same classifications:

- Intravascular Administration Set, 21CFR 880.5440, Class II, Product Codes FPA and LHI (Fluid Transfer Set)

DEVICE DESCRIPTION

The following ALARIS Medical Infusion Systems are included in this Special 510(k):

- IVAC Signature Edition Infusion Pumps & Administration Sets.
- IVAC MedSystem III Multi-Channel Infusion Pump & IVAC MedSystem III Multi-Channel Infusion Pump with DLE & Administration Sets.
- IMED Gemini Infusion Pumps/Controllers & Administration Sets.
- ALARIS Medical Medley Medication Management System & Administration Sets.
- IVAC, IMED, and ALARIS Medical Gravity, Extension, Components, & Secondary Administration Sets.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

ALARIS Medical Systems, Inc.

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This Special 510(k) submission only affects the labeling of the Administration Set portion of ALARIS Medical Infusion Systems. The labeling will be updated to improve consistency and customer satisfaction by removing non-essential information and providing guidance for the clinician that is unique to the infusion system being used and relevant to the clinician's expectations and needs. This modification will also serve to better represent ALARIS Medical Infusion System products as used in today's healthcare environment and provide a better competitive comparison with other infusion systems.

SUBSTANTIAL EQUIVALENCE

The intended use, typical applications, and fundamental scientific technology for ALARIS Medical Infusion Systems have not changed with this Special 510(k) submission, therefore we believe substantial equivalence has been established.

INTENDED USE

This Special 510(k) submission does not change the intended use for ALARIS Medical Infusion Systems. ALARIS Medical Infusion Systems are intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Ms. Renne L. Fluet
Principal Regulatory Affairs Specialist
ALARIS Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K022209
Trade/Device Name: ALARIS Medical Infusion System Administration Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA and LHI
Dated: July 3, 2002
Received: July 8, 2002

Dear Ms. Fluet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K022209 **(To Be Assigned By FDA)**

Device Trade Name: **ALARIS Medical Infusion Systems**

Indications for Use:

The following ALARIS Medical Infusion Systems are intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products:

- IVAC® Signature Edition® Infusion Pumps and Administration Sets.
- IVAC® MedSystem III® Multi-Channel Infusion Pump and IVAC MedSystem III® Multi-Channel Infusion Pump with DLE and Administration Sets.
- IMED® Gemini Infusion Pumps/Controllers and Administration Sets.
- ALARIS Medical Medley™ Medication Safety System and Administration Sets.
- IVAC®, IMED®, and ALARIS® Gravity, Extension, Components, and Secondary Administration Sets.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022209